LABEL IN PART: (Vial) "30 cc Sterile Solution Each cc contains Anterior Pituitary. . . . 25 gr. Whole Ovarian. . . . 55 gr. Chlorobutanol 0.5% Note: There is no scientific evidence available that this product has therapeutic or physiologic activity. For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription."

LIBELED: 8–6–54, S. Dist. Ohio.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 9–15–54. Default—destruction.

4645. Aqueous extract of anterior pituitary. (F. D. C. No. 37297. S. No. 83–980 L.)

QUANTITY: 26 vials at Kansas City, Mo.

SHIPPED: Between 6–1–52 and 8–13–53, from Kansas City, Mo., by Ashe Lockhart, Inc., to Minneapolis, Minn., and from there reshipped to the consignee's Kansas City office.

LABEL IN PART: (Vial) "10 c. c. Aqueous Extract of Anterior Pituitary Each c. c. contains water soluble extractives from 18½ grains fresh tissue. Contains .5% Chlorobutanol (Chloroform Derivative)."

LIBELED: On or about 10–14–54, W. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 12–31–54. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4646. Phenobarbital tablets. (F. D. C. No. 37344. S. No. 77–275 L.)

QUANTITY: 1,100 100-tablet btls. and 1 10,000-tablet tin at Skillman, N. J.

SHIPPED: 10–19–53, from Brooklyn, N. Y., by Robin Pharmacal Corp.

RESULTS OF INVESTIGATION: The tablets had been shipped in bulk; and, upon receipt by the consignee, a number of the tablets were repackaged into bottles.

LIBELED: 11–10–54, Dist. N. J.

CHARGE: 501 (b)—the strength and quality of the article when shipped differed from the standard for phenobarbital tablets set forth in the United States Pharmacopeia since the article failed to meet the test for permissible variations in the weight of individual tablets and some tablets contained more and some tablets contained less than the declared amount of phenobarbital.

DISPOSITION: 12–10–54. Default—destruction.

4647. Triple hormone suspension. (F. D. C. No. 37464. S. No. 63–593 L.)

QUANTITY: 80 vials at Memphis, Tenn.

SHIPPED: 7–19–54, from Chicago, Ill., by Maizel Laboratories.

LABEL IN PART: "10 cc. Vial Intramuscular * * * Triple Hormone Suspension Each cc. Contains: Estradiol 1.2 Mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 77 percent of the labeled amount of estradiol.

LIBELED: 12–8–54, W. Dist. Tenn.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported or was represented to possess since it contained less than the declared amount of estradiol; and, 502 (a)—the label statement "Each cc. Contains: Estradiol 1.2 Mg." was false and misleading.

DISPOSITION: 4–4–55. Consent—claimed by Maizel Laboratories and relabeled.

4648. Ethinyl estradiol tablets. (F. D. C. No. 37380. S. No. 60–196 L.)

QUANTITY: 659 100-tablet btls. at Miami, Fla.

SHIPPED: 8–13–54, from Brooklyn, N. Y., by Bonded Laboratories, Inc.

LABEL IN PART: (Btl.) "Estorals A brand of Ethinyl-Estradiol."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 46 percent of the labeled amount of ethinyl estradiol.

LIBELED: 11–24–54, S. Dist. Fla.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported and was represented to possess since it contained less than the declared amount of ethinyl estradiol per tablet; and, 502 (a)—the label statement "Each tablet contains 0.05 mg. crystalline pure Ethinyl-Estradiol" was false and misleading.

DISPOSITION: 1–7–55. Default—destruction.

4649. Betathionate. (F. D. C. No. 37438. S. No. 56–281 L.)

QUANTITY: 28 cartoned vials at Columbus, Ohio.

SHIPPED: 8–23–54, from Philadelphia, Pa., by Addison Laboratories.

LABEL IN PART: (Vial) "30 cc. Multiple Dose Vial Betathionate."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 11 times more than the declared amount of niacinamide and less than 53 percent of the declared amount of vitamin B_1 (thiamine Hcl.).

LIBELED: 11–22–54, S. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article when shipped differed from that which it purported or was represented to possess, namely, 1 mg. of niacinamide and 15 mg. of vitamin B_1 per cubic centimeter; and, 502 (a)—the label statement "Each cc. Contains: * * * Niacinamide 1 Mg. * * * Thiamine Hcl. 15 Mg." was false and misleading.

DISPOSITION: 1–11–55. Default—destruction.

4650. Estivin. (F. D. C. No. 37397. S. No. 18–480 L.)

QUANTITY: 10 cartons, 6 cartoned btls. each, at Los Angeles, Calif.

SHIPPED: 1–22–54, from New York, N. Y., by Schieffelin & Co.

LABEL IN PART: (Cartoned btls.) "0.25 Fl. Oz. List No. 3684 Estivin Dropak Contains A Processed Infusion of Rosa Gallica L (Rose Petals) For The Eyes."

LIBELED: 11–8–54, S. Dist. Calif.

CHARGE: 501 (c)—the purity and quality of the article when shipped fell below that which it purported and was represented to possess since the article was represented as possessing such purity and quality as would render it suitable for use in the eyes, whereas it was heavily contaminated with living micro-organisms so that it was not suitable for use in the eyes.

DISPOSITION: 12–2–54. Default—destruction.